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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/587,429 | 04/23/2007 | Ralph Koschinsky | ACIZ-328-301 | 8163 |

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ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

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| EXAMINER |
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MENDEZ, MANUEL A

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| ART UNIT | PAPER NUMBER |
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3763

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| MAIL DATE | DELIVERY MODE |
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08/31/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/587,429 | Applicant(s) KOSCHINSKY ET AL. | |
| | Examiner Manuel A. Mendez | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/14/2010 and 07/08/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,10,13-15,18,22,25,28,29,36,37,39,45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 9-10, 13-15, 18, 22, 25, 28-29, 36-37, 39, and 45-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>07/08/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 18, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by **Beck** (US 20020035345).

The cited patent shows in figures 1 and 2 above, an infusion system comprising:

- a platform;
- a retainer including a malleable characteristic (flexible) and being operably connected to the platform;
- a conductor being operably connected to the platform, the conductor further being electrically coupled within the iontophoretic drug delivery system;
- a dose controller being operably coupled to the conductor; and,
- a drug delivery matrix being operably connected to the platform and proximate the conductor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 9-10, 13-15, 18, 22, 25, 28-29, 36-37, 39, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Burson** et al. (US 6,615,078; hereafter Burson) in view of **Henley** (US 5,415,629), or **Neubauer** et al. (US 5,255,692; hereafter Neubauer), and in further view of **Beck** (US 20020035345).

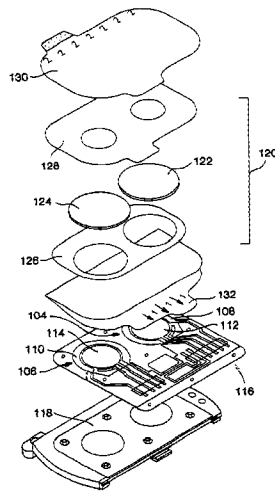


FIG. 1

The Burson patent shows in figure 1, an infusion system comprising:

- a platform;
- a retainer including a malleable characteristic (flexible) and being operably connected to the platform;
- a conductor being operably connected to the platform, the conductor further being electrically coupled within the iontophoretic drug delivery system;
- a dose controller being operably coupled to the conductor; and,
- drug delivery means being operably connected to the platform and proximate the conductor.

The Burson patent does not disclose a drug infusion matrix and is silent as to the flexibility of the entire apparatus. However, these enhancements to iontophoretic patches would have been considered conventional in the art as evidenced by the teachings of Henley, Neubauer, or Beck.

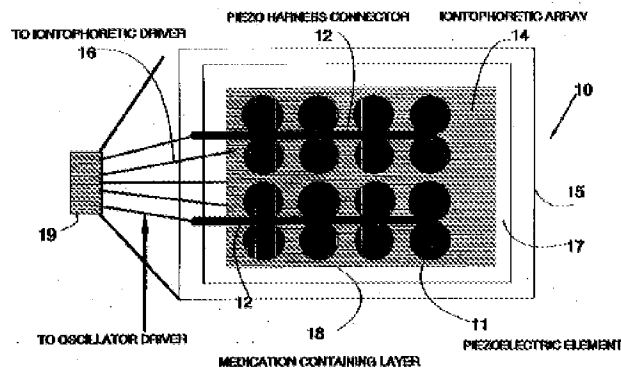


FIG. 1

In figure 1 above, the Henley patent shows a drug delivery matrix that is connected to a platform and in proximity to a conductor. In relation to the use of adhesives, the specification of Henley mentions in various sections the use of adhesives to keep together various sections of the infusion system.

Finally, in relation to the overall flexibility characteristics of the infusion system, and specifically, the shape memory characteristic of the electrode assembly, the Neubauer patent demonstrates the conventionality of designing electrode assemblies having shape/structural memory. In column 5, line 48, the specification of this patent indicates that designing electrode structures having structural memory qualities facilitates implantation and fixation of the structures in the body. Moreover, Beck expressly discloses as one of the objects of the invention [0023] is to "provide an apparatus which is flexible and capable of conforming to the surface upon which it is placed."

Based on the above observations, for a person of ordinary skill in the art, modifying the apparatus disclosed by Burson with a drug infusion matrix, as taught by Henley, and moreover, with a structure having shape memory and malleable

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characteristics, as taught by Neubauer or Beck, would have been considered obvious in the art in view of the proven conventionality of these enhancements, and moreover, because an infusion matrix would have resulted in a more efficient means of drug distribution and shape memory and malleability would have facilitated the deployment of the apparatus on the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM